

Patent  
SYR-DPP-IV-5004-C3

## IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re the Application of:

Jun Feng et al.

Serial No.: 10/809,638

Filed: March 24, 2004

For: DIPEPTIDYL PEPTIDASE  
INHIBITORS

Group Art Unit: 1614

Examiner: Not Yet Assigned

## INFORMATION DISCLOSURE STATEMENT

Mail Stop Amendment  
Commissioner for Patents  
P.O. Box 1450  
Alexandria, VA 22313-1450

Sir:

In accordance with 37 CFR §§ 1.97 and 1.98, the items identified in this Information Disclosure Statement ("IDS") are brought to the attention of the Office. The items are listed on the attached form PTO-1449, and copies are included for the Examiner's convenience. As the Office no longer requires copies of U.S. patents and applications, the U.S. copies are not being submitted with this IDS. However, if the Examiner would like copies of the U.S. cited references, Applicants will provide the references upon request. The item listed on the attached form PTO-1449 at "EN" is a non-English language article. In accordance with 37 CFR § 1.98(a)(3)(i), the following is a concise explanation of the relevance of this article:

The article by P.O. Bezuglyi relates to the synthesis of arylsulfonyl hydrazides of 3-R-quinazolone-4-carbonyl-2-acid.

The items identified in this IDS may or may not be "material" pursuant to 37 CFR § 1.56. The submission thereof by Applicant is not to be construed as an admission that any such patent, publication or other information referred to therein is material or considered to be material (37 CFR § 1.97(h)), or even qualifies as "prior art" under 35 USC § 102 with respect to this invention unless specifically designated by Applicants as such.

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Substitute for form 1449A/PTO				<b>Complete if Known</b>	
<b>INFORMATION DISCLOSURE STATEMENT BY APPLICANT</b>  (use as many sheets as necessary)				Application Number	10/809,638
				Filing Date	March 24, 2004
				First Named Inventor	Jun Feng
				Group Art Unit	1614
				Examiner Name	Not Yet Assigned
Sheet	1	of	10	Attorney Docket Number	SYR-DPP-IV-5004-C3

U.S. PATENT DOCUMENTS					
Examiner Initials *	Cite No. <sup>1</sup>	Document Number	Publication Date/ Issue Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear
		Number - Kind Code <sup>2</sup> (if known)			
	AA	US1974/3823135	07-09-1974	Pilgram et al.	
	AB	US1996/5512549	04-30-1996	Chen et al.	
	AC	US1996/5580979	12-03-1996	Bachovchin	
	AD	US1997/5614492	03-25-1997	Habener	
	AE	US2000/6156739	12-5-2000	Griffin et al.	
	AF	US2000/6166063	12-26-2000	Villhauer	
	AG	US2001/6258597-B1	07-10-2001	Bachovchin	
	AH	US2001/0020006-A1	09-06-2001	Demuth et al.	
	AI	US2001/6303661-B1	10-16-2001	Demuth et al.	
	AJ	US2001/6319893-B1	11-20-2001	Demuth et al.	
	AK	US2001/0051646-A1	12-13-2001	Demuth et al.	
	AL	US2002/0049153-A1	04-25-2002	Bridon et al.	
	AM	US2002/0049164-A1	04-25-2002	Demuth et al.	
	AN	US2002/6380398-B2	04-30-2002	Kanstrup et al.	
	AO	US2002/0082427-A1	06-27-2002	Demuth et al.	
	AP	US2002/6448045-B1	09-10-2002	Levine et al.	
	AQ	US2002/0198242-A1	12-26-2002	Demuth et al.	
	AR	US2002/0198380-A1	12-26-2002	Belzer et al.	
	AS	US2002/6500804-B2	12-31-2002	Demuth et al.	
	AT	US2003/0008925-A1	01-09-2003	Demuth et al.	
	AU	US2003/6548481-B1	04-15-2003	Demuth et al.	
	AV	US2003/0092630-A2	05-15-2003	Demuth et al.	
	AW	US2003/0119750-A1	06-26-2003	Demuth et al.	
	AX	US2003/0130199-A1	07-10-2003	von Hoersten et al.	
	AY	US2003/0134802-A1	07-17-2003	Demuth et al.	
	AZ	US2003/0135023-A1	07-17-2003	Demuth et al.	
	BA	US2003/0148961-A1	08-07-2003	Heiser et al.	
	BB	US2003/0153509-A1	08-14-2003	Bachovchin et al.	
	BC	US2003/0162820-A1	08-28-2003	Demuth et al.	
	BD	US2003/0166578-A1	09-04-2003	Arch et al.	
	BE	US2003/6620910-B1	09-16-2003	Calas et al.	
	BF	US2003/0176357-A1	09-18-2003	Pospisilik et al.	
	BG	US2003/0199451-A1	10-23-2003	Mogensen et al.	
	BH	US2003/0199672-A1	10-23-2003	Knudsen et al.	

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1 Applicant's unique citation designation number (optional). 2 Applicant is to place a check mark here if English language Translation is attached. This collection of information is required by 37 CFR 1.98. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 2 hours to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.

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				Examiner Name	Not Yet Assigned
Sheet	2	of	10	Attorney Docket Number	SYR-DPP-IV-5004-C3

	BI	US2003/0236272-A1	12-25-2003	Richard David Carr	
	BJ	US2004/6703238-B2	03-09-2004	Bachovchin	
	BK	US2004/0054171-A1	03-18-2004	Jensen et al.	
	BL	US2004/0058876-A1	03-25-2004	Hoffmann et al.	
	BM	US2004/0132732-A1	07-08-2004	Han et al.	
	BN	US2004/0167191-A1	08-26-2004	Demuth et al.	
	BO	US2004/0171555-A1	09-02-2004	Demuth et al.	

FOREIGN PATENT DOCUMENTS						
Examiner Initials*	Cite No. <sup>1</sup>	Foreign Patent Document	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear	T <sup>6</sup>
		Country Code <sup>3</sup> - Number <sup>4</sup> - Kind Code <sup>5</sup> (if known)				
	BP	FR 2.162.106 (English Abstract-1973)	11-30-1972	Amschler et al.		
	BQ	WO 89/10701	11-16-1989	BASF		
	BR	EP 0378255-A2	07-18-1990	Janssen Pharmaceutica		
	BS	GB 2230527-A	10-24-1990	Imperial Chemical Industries Plc		
	BT	WO 91/12001	08-22-1991	Merck & Co., Inc.		
	BU	WO 93/21162	01-28-1993	Nissan Chemical Industries, Ltd.		
	BV	WO 93/08259 (A2)	04-29-1993	New England Medical Center Hospitals, Inc.		
	BW	WO 93/08259 (A3)	04-29-1993	New England Medical Center Hospitals, Inc.		
	BX	EP 0547442-A1	06-23-1993	E.R. Squibb & Sons, Inc.		
	BY	WO 94/03055	02-17-1994	U.S. Government, Secty. HHS		
	BZ	EP 0587377-A2	03-16-1994	Eli Lilly and Company		
	CA	WO 95/35031	12-28-1995	La Trobe University		
	CB	WO 96/32384	10-17-1996	Taiho Pharmaceutical Co., Ltd.		
	CC	WO 96/38550	12-05-1996	Dana-Farber Cancer Institute, Inc.		
	CD	WO 97/40832	11-06-1997	Hans-Knoll-Institut Fur Naturstoff		
	CE	JP 9295977	11-18-1997	Terumo Corp.		
	CF	WO 98/00439	01-08-1998	Trustees of Tufts College		
	CG	WO 98/24780	06-11-1998	Amgen Inc.		
	CH	WO 99/16864	04-08-1999	Point Therapeutics, Inc.		
	CI	WO 99/38501	08-05-1999	Trustees of Tufts University		

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				Examiner Name	Not Yet Assigned
Sheet	3	of	10	Attorney Docket Number	SYR-DPP-IV-5004-C3

CJ	WO 99/50249	10-07-1999	Du Pont Pharmaceuticals Company
CK	WO 99-61431	12-02-1999	Probiodrug
CL	WO 99/67278	12-29-1999	Pro-Biodrug
CM	WO 99/67279	12-29-1999	Pro-Biodrug
CN	WO 00/07617	02-17-2000	Novo Nordisk
CO	WO 00/09666	02-24-2000	U.S. Government, Secty. HHS
CP	WO 00/15211	03-23-2000	Akesis Pharmaceuticals, Inc.
CQ	WO 00/76986-A1	04-11-2000	Probiodrug
CR	WO 00/34241	06-15-2000	Novartis AG
CS	WO 00/47219	08-17-2000	Ontogeny, Inc.
CT	WO 00/53171	09-14-00	Molteni L. E C. Dei Fratelli Alitti Societa' Di Esercizio S.P.A.
CU	WO 00/57721	10-05-2000	Akesis Pharmaceuticals, Inc.
CV	WO 01/14318-A2	03-01-2001	Probiodrug
CW	WO 01/34594-A1	05-17-2001	Guilford Pharmaceuticals, Inc.
CX	WO 01/52825-A2	07-26-2001	Novartis AG
CY	WO 01/56988-A1	08-09-2001	Kirin Beer Kabaushiki Kaisha
CZ	WO 01/70729-A1	09-27-2001	Sanofi-Syhelabo
DA	WO 01/97808-A1	12-27-2001	Smithkline Beecham PLC
DB	WO 02/34242-A2	05-02-2002	Probiodrug AG
DC	WO 02/34243-A2	05-02-2002	Probiodrug AG
DD	WO 02/083109-A1	10-24-2002	Ferring BV
DE	JP 2002/338466	11-27-2002	Tanabe Seiyaku Co Ltd
DF	WO 03/002593-A2	01-09-2003	Probiodrug AG
DG	WO 03/002595-A2	01-09-2003	Probiodrug AG
DH	WO 03/002596-A2	01-09-2003	Probiodrug AG
DI	WO 03/016335-A2	02-27-2003	Probiodrug AG
DJ	WO 03/022871-A2	03-20-2003	Probiodrug AG
DK	WO 03/026652-A1	04-03-2003	Bristol-Myers Squibb Company
DL	WO 03/030946-A1	04-17-2003	Novartis AG
DM	WO 03/033524-A2	04-24-2003	Probiodrug AG
DN	JP 2003/128551	05-08-2003	Sankyo Co LTD
DO	WO 03/040174-A2	05-15-2003	Probiodrug AG
DP	WO 03/045228-A2	06-05-2003	Trustees of Tufts College
DQ	WO 03/045977-A2	06-05-2003	Trustees of Tufts College
DR	WO 03/048081-A2	06-12-2003	Bristol-Myers Squibb Company
DS	WO 03/048158-A1	06-12-2003	Bristol-Myers Squibb Company
DT	WO 03/057200-A2	07-17-2003	Novo Nordisk

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				Examiner Name	Not Yet Assigned
Sheet	4	of	10	Attorney Docket Number	SYR-DPP-IV-5004-C3

	DU	WO 03/063903-A2	08-07-2003	Probiobrug AG		
	DV	WO 03/072556-A1	09-04-2003	Probiobrug AG		
	DW	WO 03/082898-A2	10-09-2003	Probiobrug AG		
	DX	WO 03/092605-A2	11-13-2003	Trustees of Tufts College		
	DY	WO 03/099279-A1	12-04-2003	Novartis AG		
	DZ	WO 03/099818-A1	12-04-2003	Chiron Corporation		
	EA	WO 03/106416-A2	12-24-2003	Smithkline Beecham Corporation		
	EB	WO 2004/017989-A1	03-04-2004	Probiobrug AG		
	EC	JP 2004/99600-A	04-02-2004	Sankyo Co. Ltd.		
	ED	WO 2004/031374-A2	04-15-2004	Probiobrug AG		
	EE	JP 2004/123738-A	04-22-2004	Takeda Chem Ind Ltd		
	EF	WO 2004/037176-A2	05-06-2004	Bristol-Myers Squibb Company		

OTHER PRIOR ART – NON PATENT LITERATURE DOCUMENTS				
Examiner Initials *	Cite No. <sup>1</sup>	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.	T <sup>2</sup>	
	EG	ARGAUD, DORIANE et al., Metaformin decreases gluconeogenesis by enhancing the pyruvate kinase flux in isolated rat hepatocytes, European J. Biochem. 213, 1341-1348 (1993).		
	EH	ASHCROFT, STEPHEN J.H. et al., Structure-activity relationships of alloxan-like compounds derived from uric acid, Br. J. Pharmac. (1986), 89 pp. 469-472.		
	EI	BAL, GUNTHER, Dipeptidyl Peptidase IV and Prolyl Oligopeptidase: Design, Synthesis and Evaluation of Substrates and Inhibitors, (2002) Universiteit Antwerpen.		
	EJ	BARAKAT, S.E.S., Synthesis and hypoglycemic activity of some new 3-[4- [[[cyclohexylamino) carbonyl] amino]sulfonyl]phenyl]-4(3H)-quinazolinones, Az. J. Pharm. Sci., Vol. 25, (2000), pp. 48-57.		
	EK	BARAKAT, S.E.S., Synthesis and Hypoglycemic Activity of Some New 4(3H) -Quinazolinone Analogues, Saudi Pharmaceutical Journal, Vol. 8, No.4 (2000) pp.198-204.		
	EL	BAKER, B.R. et al., Irreversible Enzyme Inhibitors. On the Mode of Pyrimidine Binding of 5-alkyl and 5-Arylpyrimidines to Dihydrofolic Reductase (1,2), Journal of Heterocyclic Chemistry Vol. 4 (1967) pp. 39-48.		
	EM	BELGODERE, ELENA et al., Synthesis of Substituted Pyrimidines, Study of the Structure and of the Tautomeric Equilibria, (1976) Chem. Abstracts, Columbus, OH Vol. 85 No. 9.		
	EN	BEZUGLYI, P.O. et al., Synthesis of arylsulfonyl hydrazide of 3-R-quinazolone-4-carbonyl-2-acid, Pharmaceutical Journal (1979), pp. 70-71.		

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Sheet	5	of	10	Attorney Docket Number	SYR-DPP-IV-5004-C3

EO	BHADURI, A.P. et al., Urinary Metabolite of 2-Piperazino-3 (H)-4-Quinazalone (Centiperalone), A Potent Blood Sugar Lowering Agent, Indian J. Biochem. Biophys., Vol. 12 (1975), pp. 413-414.	
EP	BOURAS, MOHAMMED, et al., Metabolism of enterostatin in rat intestine, brain, membranes and serum: differential involvement of proline-specific peptidases, Peptides, Vol. 16, No. 3, (1995), pp. 399-405.	
EQ	BRUN, JEAN-FREDERIC, et al., Effects of Oral Zinc Gluconate on Glucose Effectiveness and Insulin Sensitivity in Humans, Biological Trace Element Research Vol. 47 (1995), pp. 385-391.	
ER	BUCKLEY, DI, Analysis of the Degradation of Insulinotropin [GLP-1 (7-37)] In Human Plasma and Production of Degradation Resistant Analogs.	
ES	CHATTERJEE, A.K. et al., Effect of Centiperalone in Insulin Deficient Diabetes, Indian Journal of Experimental Biology Vol. 18 (1980), pp. 1005-1008.	
ET	CHATTERJEE, A.K. et al., Effect of Centiperalone, a New Hypoglycemic Agent on Insulin Biosynthesis & Release from Isolated Pancreatic Islets of Rat, Indian Journal of Experimental Biology Vol. 20 (1981) pp.270-272.	
EU	COPPOLA, GARY M. et al., 1-Aminomethylisoquinoline-4-carboxylates as Novel Dipeptidylpeptidase IV Inhibitors, Bioorganic & Medicinal Chemistry Letters Vol. 10 (2000), pp. 1555-1558.	
EV	DEACON, CAROLYN F. et al., Degradation of Glucagon-Like Peptide 1 <i>in Vitro</i> Yields an N-Terminally Truncated Peptide That is a Major Endogenous Metabolite <i>in Vivo</i> , Journal of Clinical Endocrinology and Metabolism Vol. 80, No. 3 (1995), pp. 952-957.	
EW	DEACON, CAROLYN F. et al., Both Subcutaneously and Intravenously Administered Glucagon-Like Peptide I Are Rapidly Degraded From the NH <sub>2</sub> -Terminus in Type II Diabetic Patients and in Healthy Subjects, Diabetes, Vol. 44 (1996), pp. 1125-1131.	
EX	DEACON, CAROLYN F. et al., Dipeptidyl peptidase IV Inhibition Influences GLP-1 Metabolism in Vivo, Regulatory Peptides Vol. 64 Issues 1-3 (1996) p.30.	
EY	DEACON, CAROLYN F. et al., Dipeptidyl peptidase IV Inhibition Potentiates the Insulinotropic Effect of Glucagon-Like Peptide 1 in the Anesthetized Pig, Diabetes, Vol. 47 (1998), pp. 764-769.	
EZ	DEACON, CAROLYN F. et al., Dipeptidyl peptidase IV Inhibition as an Approach to the Treatment and Prevention of Type 2 Diabetes: a Historical Perspective, Biochemical and Biophysical Research Communications 294 (2002), pp. 1-4.	
FA	DEMUTH, HANS-ULRICH et al., Rebuttal to Deacon and Holst: "Metaformin effects on dipeptidyl peptidase IV degradation of glucagons-like peptide-1" versus "dipeptidyl peptidase inhibition as an approach to the treatment and prevention of type 2 diabetes: a historical perspective" Biochemical and Biophysical Research Communications 296 (2002) pp. 229-232.	
FB	ENGEL, MICHAEL et al., The crystal structure of dipeptidyl peptidase IV (CD26) reveals its functional regulation and enzymatic mechanism, Proc. Nat. Acad. Sci. Early Edition (2003), pp. 1-6.	
FC	FANTUS, I. GEORGE, et al., Mechanism of Action of Metformin: Insulin Receptor and Postreceptor Effects in Vitro and in Vivo, J. Clinical Endocrinology & Metabolism (1986), pp. 898-905.	

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FD	GARRATT, PETER J. et al., A Novel Synthesis of Dihydropyrimidines, J. Chem. Soc., Chem. Commun. (1987), pp.568-569.
FE	GARRATT, PETER J. et al., One-Carbon Compounds as Synthetic Intermediates. The Synthesis of Hydropyrimidines and Hydroquinazolines by Sequential Nucleophilic Addition to Diphenyl Cyanocarbonimidate With Concomitant Cyclization, J. Org. Chem. (1988), pp. 1062-1069.
FF	GAZIT, AVIV et al., Tyrphostins IV – Highly Potent Inhibitors of EGF Receptor Kinase. Structure-Activity Relationship Study of 4- Anilidoquinazolines, Bioorganic & Medicinal Chemistry, Vol. 4, No.8 (1996) pp. 1203-1207.
FG	GUERRIERI, N., et al., Vanadium Inhibition of Serine and Cysteine Proteases, Comparative Biochemistry and Physiology Part A 122 (1997), pp.331-336.
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	HM	WIEDEMAN, PAUL E. et al., Dipeptidyl peptidase IV inhibitors for the treatment of impaired glucose tolerance and type 2 diabetes, Current Opinion in Investigational Drugs, Vol. 4, No. 4 (2003), pp. 412-420.	
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	HO	YUEN, V.G. et al., Acute and Chronic Oral Administration of Bis(maltolato)oxovanadium(IV) in Zucker Diabetic Fatty (ZDF) Rats, Diabetes Research and Clinical Practice 43 (1999), pp. 9-19.	
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